

RECEIVED
CENTRAL FAX CENTER

SAEG193.001APC

NOV 27 2006

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Ueda et al.

Appl. No. : 10/549,555

Filed : June 29, 2006

For : DRUG FOR TREATING
HEMOPHILIA AND METHOD OF
TREATING HEMOPHILIA USING
THE SAME

Examiner : Unknown

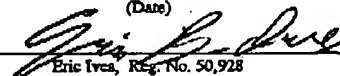
Group Art Unit: 1646

CERTIFICATE OF FAX TRANSMISSION

I hereby certify that this correspondence and all marked attachments are being facsimile transmitted to the Office of Initial Patent Examination Customer Service Center at 571-273-8300 at the U.S. Patent and Trademark Office on the date shown below:

November 27, 2006

(Date)



Eric Ives, Reg. No. 50,928

REQUEST FOR CORRECTED FILING RECEIPT

Commissioner for Patents
P.O. Box 1450
Office of Initial Patent Examination
Customer Service Center
Alexandria, VA 22313-1450

Dear Sir:

Applicant hereby requests that the Official Filing Receipt, a copy of which is enclosed, be corrected to reflect the following: in the last inventor's name, please delete "MAURINEE" and insert "MARINEE". For your convenience, a copy of the Declaration/Power of Attorney and cover page of the PCT publication is enclosed.

Appl. No. : 10/549,555
Filed : July 29, 2006

We look forward to receiving the corrected filing receipt in due course.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 11-27-2006

By: 

Eric Ives

Registration No. 50,928

Agent of Record

Customer No. 20,995

(805) 547-5580

3126943.vr
111706



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FILE FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/549,555	06/29/2006	1646	1030	SAEG193.001APC	4	10	1

CONFIRMATION NO. 3773

20995
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

RECEIVED
CENTRAL FAX CENTER

NOV 27 2006

FILING RECEIPT



OC000000019853480

Date Mailed: 07/19/2006

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Masakazu Ueda, Tokyo, JAPAN;
Shunichi Kuroda, Osaka, JAPAN;
Katsuyuki Tanizawa, Osaka, JAPAN;
Masaharu Senoo, Okayama, JAPAN;
Akihiko Kondo, Hyogo, JAPAN;
Thierry Vandendriessche, Bierboek, BELGIUM;
Maurinee Chuah, Bierboek, BELGIUM;

MARINEE

Power of Attorney: The patent practitioners associated with Customer Number 20995.

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/JP04/03560 03/17/2004

Foreign Applications

JAPAN 2003071788 03/17/2003

If Required, Foreign Filing License Granted: 07/18/2006

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is **US10/549,555**

Projected Publication Date: 10/26/2006

Non-Publication Request: No

Early Publication Request: No

Title

Drug for treating hemophilia and method of treating hemophilia using the same

Preliminary Class

435

PROTECTING YOUR INVENTION OUTSIDE THE UNITED STATES

Since the rights granted by a U.S. patent extend only throughout the territory of the United States and have no effect in a foreign country, an inventor who wishes patent protection in another country must apply for a patent in a specific country or in regional patent offices. Applicants may wish to consider the filing of an international application under the Patent Cooperation Treaty (PCT). An international (PCT) application generally has the same effect as a regular national patent application in each PCT-member country. The PCT process simplifies the filing of patent applications on the same invention in member countries, but does not result in a grant of "an international patent" and does not eliminate the need of applicants to file additional documents and fees in countries where patent protection is desired.

Almost every country has its own patent law, and a person desiring a patent in a particular country must make an application for patent in that country in accordance with its particular laws. Since the laws of many countries differ in various respects from the patent law of the United States, applicants are advised to seek guidance from specific foreign countries to ensure that patent rights are not lost prematurely.

Applicants also are advised that in the case of inventions made in the United States, the Director of the USPTO must issue a license before applicants can apply for a patent in a foreign country. The filing of a U.S. patent application serves as a request for a foreign filing license. The application's filing receipt contains further information and guidance as to the status of applicant's license for foreign filing.

Applicants may wish to consult the USPTO booklet, "General Information Concerning Patents" (specifically, the section entitled "Treaties and Foreign Patents") for more information on timeframes and deadlines for filing foreign patent applications. The guide is available either by contacting the USPTO Contact Center at 800-786-9199, or it can be viewed on the USPTO website at <http://www.uspto.gov/web/offices/pac/doc/general/index.html>.

For information on preventing theft of your intellectual property (patents, trademarks and copyrights), you may wish to consult the U.S. Government website, <http://www.stopfakes.gov>. Part of a Department of Commerce initiative, this website includes self-help "toolkits" giving innovators guidance on how to protect intellectual property in specific countries such as China, Korea and Mexico. For questions regarding patent enforcement issues, applicants may call the U.S. Government hotline at 1-866-999-HALT (1-866-999-4158).

LICENSE FOR FOREIGN FILING UNDER

Title 35, United States Code, Section 184

Title 37, Code of Federal Regulations, 5.11 & 5.15

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The

date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Bureau of Industry and Security, Department of Commerce (15 CFR parts 730-774); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

NOT GRANTED

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

(12) 特許協力条約に基づいて公開された国際出版

(19) 世界知的所有権機関
国際事務局(43) 国際公開日
2004年9月30日 (30.09.2004)

PCT

(10) 国際公開番号
WO 2004/082720 A1(51) 国際特許分類: A61K 48/00, 31/7088,
47/42, 9/51, 38/36, 38/37, A61P 7/04

(21) 国際出版番号: PCT/JP2004/003560

(22) 国際出版日: 2004年3月17日 (17.03.2004)

(25) 国際出版の言語: 日本語

(26) 国際公開の言語: 日本語

(30) 優先権データ:
特願2003-071788 2003年3月17日 (17.03.2003) JP2 Osaka (JP). 妹尾 昌治 (SENOO, Masaharu) (JP/JP);
〒7038273 岡山県岡山市門田文化町2-10-13
Okayama (JP). 近藤 昭彦 (KONDO, Akihiko) (JP/JP); 〒
6570015 兵庫県神戸市灘区松原伯母野山町1-1-
2-806 Hyogo (JP). バンデンドリエッスエシエ
リー (VANDENDRIESSCHE, Thelery) (BE/BE); B3360
コルベック ロースターレンラーン 17 Korbeek-Lo
(BE). チュア マリニー (CHUAH, Marinee) (MY/BE);
B3360 コルベック ロースターレンラーン 17 Kor-
beek-Lo (BE).(74) 代理人: 小池 晃, 外 (KOIKE, Akira et al.); 〒1000011
東京都千代田区千代田一丁目1番7号 大和生命ビ
ル11階 Tokyo (JP).(71) 出願人 (米国を除く全ての指定国について): 株
式会社ビーグル (BEACLE INC.) (JP/JP); 〒7011221
岡山県岡山市芳賀5303 岡山リサーチパーク
インキュベーションセンター314号室 Okayama
(JP). ブイアイビー (ヴァーラム インターユニバ
ルシテール インスティテュート フォア ビオテク
ノロジー) ブイジータブリュ (VIB (VLAAMS IN-
TERUNIVERSITAIR INSTITUUT VOOR BIOTECH-
NOLOGIE) VZW) (BE/BE); B9052 スピナー デリビッ
シェストラート 120 Zwijnaarde (BE). デー. コー
レン リサーチ ファウンデーション ブイジータブリュ
オンデル ビース アンナボルシグ カンパス ガス
テュイスベルグ ケー. ユー. リューベン (D. COLLEN
RESEARCH FOUNDATION VZW ONDERWIJS EN
NAVORSING CAMPUS GASTHUISER K. U. LEU-
VEN) (BE/BE); B3000 リューベン ヘーレストラート
49 Leuven (BE).(81) 指定国 (表示のない限り、全ての種類の国内保護が
可能): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR,
BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM,
DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, GR, HU,
ID, IL, IN, IS, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT,
LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI,
NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG,
SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ,
VC, VN, YU, ZA, ZM, ZW.(84) 指定国 (表示のない限り、全ての種類の広域保護が
可能): ARIPO (BW, GH, GM, KE, LS, MW, MZ, SD, SL,
SZ, TZ, UG, ZM, ZW), ユーラシア (AM, AZ, BY, KG,
KZ, MD, RU, TJ, TM), ユーロッパ (AT, BE, BG, CH, CY,
CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC,
NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG,
CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

(72) 発明者: および

(75) 発明者/出願人 (米国についてのみ): 上田 政和 (UEDA,
Masakazu) (JP/JP); 〒1620837 東京都新宿区納戸町6
Tokyo (JP). 黒田 健一 (KURODA, Shunichi) (JP/JP); 〒
5650872 大阪府吹田市上山田7番C-104号 Os-
aka (JP). 谷津 克行 (TANIZAWA, Katsuyuki) (JP/JP);
〒5630214 大阪府豊能郡豊能町希望ヶ丘2-30-

添付公開書類:

— 国際調査報告書

2文字コード及び地の略語については、定期発行される
各PCTガゼットの巻頭に掲載されている「コードと略語
のガイダンスノート」を参照。

WO 2004/082720 A1

(54) Title: DRUG FOR TREATING HEMOPHILIA AND METHOD OF TREATING HEMOPHILIA USING THE SAME

(54) 発明の名称: 血友病治療用薬剤及びそれを用いた血友病治療方法

(57) Abstract: A drug whereby a blood coagulation factor gene can be efficiently transferred into liver cells with little risk of side effects can be obtained by a convenient method comprising encapsulating a blood coagulation factor VIII (IX) gene for treating hemophilia in a hollow nanoparticle obtained by expressing a protein capable of forming particles (for example, hepatitis B virus surface antigen protein) in an eucaryotic cell.

(57) 要約: 粒子形成能を有するタンパク質、例えばB型肝炎ウイルス表面抗原タンパク質を真核細胞中で発現させることにより得られた中空ナノ粒子に、血友病治療用の血液凝固因子VIII (IX) 因子の遺伝子を包含させるという簡便な方法により、血液凝固因子の遺伝子を肝細胞に効率的に導入することができると共に副作用の心配も極めて低い薬剤を得る。

Page 1

Attorney's Docket No. SAEG193001APC

DECLARATION AND POWER OF ATTORNEY - USA PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is

sought on the invention entitled THERAPEUTIC PRODUCT FOR TREATING HEMOPHILIA AND METHOD OF TREATING HEMOPHILIA USING THE SAME

the specification of which:

- (a) ☐ is attached hereto; or
- (b) ☒ was filed on September 19, 2005 as Application No. 10/549555 or Express Mail No., as Application No. not yet known _____ and was amended on _____ (if applicable); or
- (c) ☒ was described and claimed in PCT International Application No. PCT/JP2004/003560 filed on March 17, 2004 and as amended under PCT Article 19 on _____ (if any) and/or under PCT Article 34 on _____ (if any).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above;

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56;

I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign application(s) for patent, design or inventor's certificate or any PCT international application(s) listed below and have also identified below any foreign application(s) for patent, design or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed for the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN APPLICATION(S)

COUNTRY (OR INDICATE IF PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 37 U.S.C. § 119	
Japan	2003-71788	17/03/2003	<input checked="" type="checkbox"/> YES	NO <input type="checkbox"/>
			<input type="checkbox"/> YES	NO <input type="checkbox"/>
			<input type="checkbox"/> YES	NO <input type="checkbox"/>
			<input type="checkbox"/> YES	NO <input type="checkbox"/>

Page 2

Attorney's Docket No. _____

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below, and insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code § 112, I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56, which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Prior U.S.A. Application(s)

Application No.: _____ Filing Date: _____ Status: _____

POWER OF ATTORNEY: I hereby appoint the registrants of Knobbe, Martens, Olson & Bear, LLP, 2040 Main Street, 14th Floor, Irvine, California 92614, Telephone (949) 760-0404, Customer No. 20,995.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful, false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole or first inventor: URIDA Masakazu

Inventor's signature Masakazu Urida Day 12th Month January Year 2006

Residence (city and country): Shinjuku-ku, Tokyo 1620837, Japan

Citizenship: Japan

Post Office Address: 6, Nandomachi, Shinjuku-ku, Tokyo 1620837, Japan

Full name of second inventor: KURODA Shunichi

Inventor's signature Shunichi Kuroda Day 12th Month January Year 2006

Residence (city and country): Suita-shi, Osaka 5650872, Japan

Citizenship: Japan

Post Office Address: 104, 7-C, Kamiyamada, Suita-shi, Osaka 5650872, Japan

Full name of third inventor: TANIZAWA Katsuyuki

Inventor's signature Katsuyuki Tanizawa Day 12th Month January Year 2006

Residence (city and country): Toyono-gun, Osaka 5630214, Japan

Citizenship: Japan

Post Office Address: 2-30-2, Kibougakoka, Toyono-cho, Toyono-gun, Osaka 5630214, Japan

Page 3

Attorney's Docket No. _____

Full name of fourth inventor: SENOO Masaharu

Inventor's signature Masaharu Senoo Day 12th Month January Year 2006

Residence (city and country): Okayama-shi, Okayama 7038273, Japan

Citizenship: Japan

Post Office Address: 2-10-13, Kadobunkamachi, Okayama-shi, Okayama 7038273, Japan

Full name of fifth inventor: KONDO Akihiko

Inventor's signature Akihiko Kondo Day 12th Month January Year 2006

Residence (city and country): Kobe-shi, Hyogo 6570015, Japan

Citizenship: Japan

Post Office Address: 1-1-2-806, Shinoharabanyama-cho, Nada-ku, Kobe-shi, Hyogo 6570015, Japan

Full name of sixth inventor: VANDENDRIESSCHE Thierry

Inventor's signature Thierry Vandendriessche Day 2nd Month December Year 2005

Residence (city and country): Korbeek-L, B3360, Belgium

Citizenship: Belgium

Post Office Address: Stervenlaan 17, Korbeek-L, B3360, Belgium

TIENSESTEENWEG 250, BIERBECK

Full name of seventh inventor: CHUAH Marilee

Inventor's signature Marilee Chuah Day 2nd Month December Year 2005

Residence (city and country): Korbeek-L, B3360, Belgium

Citizenship: Malaysia

Post Office Address: Stervenlaan 17, Korbeek-L, B3360, Belgium

TIENSESTEENWEG 250, BIERBECK

Full name of eighth inventor: _____

Inventor's signature _____ Day _____ Month _____ Year _____

Residence (city and country): _____

Citizenship: _____

Post Office Address: _____

Send Correspondence To:
KNOBBE, MARTENS, OLSON & BEAR, LLP
Customer No. 20,995
PF-38

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☒ **BLACK BORDERS**
- ☐ **IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- ☐ **FADED TEXT OR DRAWING**
- ☐ **BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- ☐ **SKEWED/SLANTED IMAGES**
- ☐ **COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- ☐ **GRAY SCALE DOCUMENTS**
- ☐ **LINES OR MARKS ON ORIGINAL DOCUMENT**
- ☐ **REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- ☐ **OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.